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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,072	04/03/2007	Siegfried Ansorge	PMP-0003	6887

23599 7590 06/11/2009

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
SIMMONS, CHRIS E	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
06/11/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No.	Applicant(s)	
	10/584,072	ANSORGE ET AL.	
	Examiner	Art Unit	
	CHRIS E. SIMMONS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-8 and 10-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-8 and 10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 03/24/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 1-3, 5-8 and 10-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Biewenga et al. and Mira et al., the combination taken in view of US 2004/0167153.

Applicant asserts, at page 6 of the response, that the Office action at page 4 contends that the motivation to combine lipoic acid with silibinin can be obtained from the secondary reference. For clarity, the Office action explains the rationale to combine the agents at page 5 which states, "[t]he skilled artisan would have been motivated to combine silibinin with alpha-lipoic acid by the desire to use the HOCl scavenging qualities of both compounds to prevent HOCl from ultimately increasing the tissue damaging properties of elastase since elastase activity is considered responsible for lung damage in emphysema. The artisan would also have a reasonable expectation to, at least, render an additive scavenger effect against HOCl…". Applicant further argues that nothing in either of the cited references provides a suggestion to combine the 2

agents “i.e., a free radical scavenger and an effector of glutathione metabolism”. Moreover, applicant argues that neither secondary reference give any advice for treatment of COPD with the agents as claimed. This argument is not found to be persuasive because the references clearly are directed to the HOCl antioxidative scavenging effects of silibinin (Mira reference) and lipoic acid (Biewenga reference). The disclosures of the HOCl scavenging effects of each agent provides the motivation to one of ordinary skill of reasonable expectation to have at least an additive HOCl scavenging effect when the agents are combined together. Since HOCl exacerbates the problem with increased elastase and emphysema, then it would be reasonable to use agents taught to decrease the effect of HOCl for the treatment of emphysema. Applicant asserts that the citation of *In re Kerkhoven* by the examiner to support the notion that it would have been obvious to combine ingredients known to be useful for the same purpose to form a composition useful for that same purpose is misplaced in this case. Applicant bases this assertion on the allegation that the 2 agents are not taught to be useful for the same purpose. Applicant alleges that Biewenga is directed to radical scavengers whereas the compounds of “Yeadon” (it is assumed applicant meant to refer to Mira since it is the reference relied upon to disclose the scavenging effects of silibinin) are directed to effectors of glutathione metabolism. This is not found to be persuasive because the Mira reference clearly is directed to the radical scavenging effects of silibinin and not glutathione metabolism as alleged by applicant.

As for the unexpected results, applicant refers to data exemplified in Example 4 (Table 6) and Example 5 (Table 7) which allegedly shows the combination of silibinin with lipoic acid leads to unexpected results. The examiner does not find any unexpected results in the data presented in these examples. There is no adequate side by side comparison of the closest art. Both silibinin and lipoic acid are both used for the same purpose in the examples, i.e., to increase cellular thiol expression and inducing phagocytosis. Applicant claims to have data that shows that a combination of 70 micrograms silibinin with 10 micrograms of lipoic acid demonstrates an unexpected increase in thiol expression and phagocytosis. However, applicant has compared these results to those obtained when either using 70 micrograms silibinin alone or using 10 micrograms lipoic acid alone. Since the total amount of agent used to show alleged unexpected results was 80 micrograms (i.e., 70 +10 micrograms), it would appear that a proper showing of unexpected results would also include a comparison to 80 micrograms of lipoic acid alone and 80 micrograms of silibinin alone. Applicant has not provided data showing this comparison; therefore, the showing is not considered to be a proper showing of unexpected results. Even if unexpected results were demonstrated, *in arguendo,* the claims are not commensurate in scope to any example in Tables 6 or 7.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. S./
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612